

Notice of Allowability

Application No.

09/846,588

Applicant(s)

GOLDMAN ET AL.

Examiner

Art Unit

Quang Nguyen, Ph.D.

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/17/05.
2. ☒ The allowed claim(s) is/are 1,3-6,28 and 34-37.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

EXAMINER'S AMENDMENT

Applicant's amendment After-Final filed on 10/17/05 has been entered. With respect to the proposed claims now reciting the use of both a nucleic acid construct encoding a brain-derived neurotrophic factor and a nucleic acid construct encoding noggin, this specific combination is consistent with Applicant's elected invention and was not restricted in the Restriction requirement dated 2/28/02.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with attorney Michael L. Goldman on 11/1/05.

In the claims

Please cancel claims 44 and 59-60. Claims 1, 3-6, 28 and 34-37 are amended as follows.

Claim 1 (Currently amended) A method of inducing addition of medium spiny neurons in post-natal and adult brain comprising:

providing a nucleic acid construct encoding a brain-derived neurotrophic factor and a nucleic acid construct encoding noggin, wherein the nucleic acid constructs are in viral vectors, and

injecting ~~the nucleic acid constructs~~ said viral vectors into a subject's lateral ventricles to infect the ventricular wall under conditions effective to express the neurotrophic factor and noggin and to induce addition of medium spiny neurons in any one or all of the caudate nucleus and the putamen of the subject.

Claim 3 (Currently amended) The [[A]] method according to claim 1, wherein the viral vectors [[is]] are selected from the group consisting of an adenoviral vector, a lentiviral vector, a retroviral vector, an adeno-associated viral vector, [[or]] and a combination thereof.

Claim 4 (Currently amended) The [[A]] method according to claim 1, wherein the nucleic acid construct encoding the brain-derived neurotrophic factor further comprises a constitutive promoter for controlling expression of the brain-derived neurotrophic factor.

Claim 5 (Currently amended) The [[A]] method according to claim 1, wherein the nucleic acid construct encoding the brain-derived neurotrophic factor further comprises a cell-specific promoter for controlling expression of the brain-derived neurotrophic factor.

Claim 6 (Currently amended) The [[A]] method according to claim 1, wherein the nucleic acid construct encoding the brain-derived neurotrophic factor further comprises an inducible or conditional promoter for controlling expression of the brain-derived neurotrophic factor.

Claim 28 (Currently amended) A method of inducing addition of medium spiny neurons in a subject having Huntington's disease ~~treating Huntington's Disease~~ comprising:

providing a nucleic acid construct encoding a brain-derived neurotrophic factor and a nucleic acid construct encoding noggin, wherein the nucleic acid constructs are in viral vectors, and

injecting ~~the nucleic acid constructs~~ said viral vectors into [[a]] the subject's lateral ventricles to infect the ventricular wall under conditions effective to express the neurotrophic factor and noggin and to induce addition of medium spiny neurons in any one or all of the caudate nucleus and the putamen of the subject ~~and to treat Huntington's Disease.~~

Claim 34 (Currently amended) The [[A]] method according to claim 28, wherein the viral vectors [[is]] are selected from the group consisting of an adenoviral vector, a lentiviral vector, a retroviral vector, an adeno-associated viral vector, [[or]] and a combination thereof.

Claim 35 (Currently amended) The [[A]] method according to claim 28, wherein the nucleic acid construct encoding the brain-derived neurotrophic factor further comprises a constitutive promoter for controlling expression of the brain-derived neurotrophic factor.

Claim 36 (Currently amended) The [[A]] method according to claim 28, wherein the nucleic acid construct encoding the brain-derived neurotrophic factor further

Art Unit: 1633

comprises a cell-specific promoter for controlling expression of the brain-derived neurotrophic factor.

Claim 37 (Currently amended) The [[A]] method according to claim 28, wherein the nucleic acid construct encoding the brain-derived neurotrophic factor further comprises an inducible or conditional promoter for controlling expression of the brain-derived neurotrophic factor.

REASONS FOR ALLOWANCE:

The following is an examiner's statement of reasons for allowance: The prior art of record does not teach or fairly suggest a method of inducing addition of medium spiny neurons in post-natal and adult brain or in a subject having Huntington's disease by injecting recombinant viral vectors encoding a brain-derived neurotrophic factor and noggin into a subject's lateral ventricles to infect the ventricular wall under conditions effective to express the neurotrophic factor and noggin and to induce addition of medium spiny neurons in any one or all of the caudate nucleus and the putamen of the subject. Additionally, the amended claims obviate the rejection under 35 U.S.C. 112, first paragraph as evidenced by the Declarations filed under 37 C.F.R. 1.132 on 12/27/04 and 12/6/04. Accordingly, the claims are allowable over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, Celine Qian, Ph.D., may be reached at (571) 272-0777, or SPE, Dave Nguyen, at (571) 272-0731.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within

Art Unit: 1633

5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

Quang Nguyen, Ph.D.

A handwritten signature in black ink, appearing to read 'Dave', with a long horizontal stroke extending to the right.

**DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER**